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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/522,456

01/21/2005

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JAB1715-US-PCT

4146

27777 7590 10/06/2010
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EXAMINER

AHMED, HASAN SYED

ART UNIT

PAPER NUMBER

1615

NOTIFICATION DATE

DELIVERY MODE

10/06/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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DETAILED ACTION

Receipt is acknowledged of applicants' amendment, remarks, and supplemental IDS filed on 12 February 2010 and amendment filed on 14 June 2010.

* * * * *

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, and 15 remain rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 6,211,249 ("Cohn") (cited on the IDS filed on 21 January 2005).

Instant claim 1 recites a diblock copolymer of formula A-B wherein polymer block A represents a linear pharmaceutically acceptable hydrophilic polymer with a molecular weight <1,000, and polymer block B represents a polymer comprising at least two different monomers selected from glycolic acid, propiolactone, gamma-butyrolactone, delta-valerolactone, gamma-valerolactone, epsilon-caprolactone, trimethylene carbonate, p-dioxanone, tetramethylene carbonate, epsilon-lactone, 1,5-dioxepan-2-one wherein the diblock copolymer is liquid at a temperature below 50 degrees Celsius.

Cohn discloses polymeric compositions comprising coupled or cross-linked poly(ester)/polyether AB diblocks (see col. 2, lines 30-32). In a preferred embodiment, the polyester unit A is derived from the polymerization of monomers selected from, *inter alia*, glycolic acid (see col. 2, line 42), epsilon-caprolactone (see col. 2, line 43), and

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mixtures thereof (see col. 2, lines 53-54) (reading on instant claims 1 and 2). Cohn further discloses that unit B is a poly(oxyalkylene) molecule with a molecular weight as low as 100 (diethylene glycol) and a preferred molecular weight as low as 550 (see col. 3, lines 1-5) (reading on claim 1).

Regarding the temperatures recited in instant claims 1 and 15, Cohn is silent with respect to the melting points of the disclosed diblock polymers. However, the diblock polymers disclosed in the Cohn reference read on the instant diblock polymers, as currently claimed (see above). “‘Products of identical chemical composition can not have mutually exclusive properties.’ A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).” See MPEP 2112.01.

* * * * *

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1 and 12-14 remain rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,211,249 (“Cohn”) (cited on the IDS filed on 21 January 2005).

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The features of instant claim 1 disclosed in Cohn are discussed above. Cohn further teaches that the disclosed diblock polymer may have a molecular weight range of, "as low as several hundred to upwards of 50,000 or more." See col. 38, lines 21-23. This disclosed range overlaps with the molecular weight ranges recited in instant claims 12-15. In the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a prima facie case of obviousness exists. In re Wertheim, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); In re Woodruff, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to disclose a diblock copolymer of formula A-B wherein polymer block A represents a linear pharmaceutically acceptable hydrophilic polymer with a molecular weight <1,000, and polymer block B represents a polymer comprising at least two different monomers selected from, *inter alia*, glycolic acid and epsilon-caprolactone, wherein the diblock copolymer has a molecular weight ranging from 2000 to 10,000 as taught by Cohn. One of ordinary skill in the art at the time the invention was made would have been motivated to make such a copolymer because it may be used to make, "bioabsorbable polymeric material which can be produced in a variety of formulations which have acceptable strength, may be reactive or non-reactive with patient tissue depending upon the desired application, and are bioabsorbable" as explained by Cohn (see col. 2, lines 10-14).

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Response to Arguments

Applicants' arguments filed on 12 February 2010 have been fully considered but they are not persuasive.

Applicants argue that "...the prior art is clearly a solid composition..." See remarks, page 3.

Examiner respectfully disagrees. The composition of Example 1 is disclosed as a liquid at room temperature (see col. 39, lines 49-50).

Applicants argue that Cohn teaches diblock copolymers that are used as building blocks for more complex polymeric structures. See remarks, page 4.

The applicants' arguments are based on what the examiner believes to be a narrow interpretation of the prior art. A reference may be relied upon for all that it would have reasonably suggested to one having ordinary skill the art, including non-preferred embodiments. *Merck & Co. v. Biocraft Laboratories*, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), *cert. denied*, 493 U.S. 975 (1989). Cohn explicitly states that "[t]he AB diblocks described above may be utilized without further modification..." (see col. 3, lines 6-7).

Applicants argue that Cohn does not teach stable micelles. See remarks, pages 4-5.

It is noted that the features upon which applicant relies (i.e., stable micelles) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HASAN S. AHMED whose telephone number is (571)272-4792. The examiner can normally be reached on 9am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on (571)272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/H. S. A./
Examiner, Art Unit 1615

/Humera N. Sheikh/
Primary Examiner, Art Unit 1615